

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division**

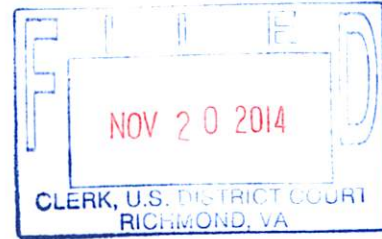
HEALTH DIAGNOSTIC LABORATORY, INC.

Plaintiff,

v.

BOSTON HEART DIAGNOSTICS CORPORATION

Defendant.



Case No. 3:14cv796

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiff Health Diagnostic Laboratory, Inc. ("HDL") files this Complaint for patent infringement against Defendant Boston Heart Diagnostics Corporation ("Boston Heart") under 35 U.S.C. § 271(a). HDL hereby alleges as follows:

PARTIES AND JURISDICTION

2. HDL is a Virginia corporation with its principal place of business at 737 North 5th Street, Suite 103, Richmond, Virginia 23219. HDL is a laboratory testing company that provides clinical laboratory tests of biomarkers for cardiovascular, diabetes, and related diseases. HDL's products and services provide for risk assessment and early detection of these disease states.

3. Boston Heart is a Delaware corporation with its principal place of business at 175 Crossing Boulevard, Framingham, Massachusetts 01702. On information and belief, Boston Heart is a health care company that provides diabetes disease management through a combination of diagnostic tools, including its Boston Heart Prediabetes AssessmentTM. Boston

Heart's business extends throughout the United States and the Commonwealth of Virginia through its website at <http://www.bostonheartdiagnostics.com>.

4. This Court has personal jurisdiction over Boston Heart by virtue of its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to HDL, which is a Virginia corporation. On information and belief, Boston Heart actively solicits health care providers, physicians, and patients, and maintains substantial commercial relationships and agreements with health care providers in Virginia. On information and belief, Boston Heart, through its employees and agents, serves physicians and patients in Virginia through a highly interactive website. On information and belief, Boston Heart specifically targets this District through its website that permits patients, including Virginia residents, to access personal account information.

5. On information and belief, Boston Heart derives revenues from the products and services offered in Virginia and throughout the United States such that it should have reasonably expected to be subject to suit in this District.

6. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '358 Patent Under 35 U.S.C. § 271(a))

7. HDL realleges and incorporates by reference paragraphs 1-6.

8. United States Patent No. 8,119,358 ("the '358 patent"), titled "Diabetes-Related Biomarkers and Methods of Use Thereof," was duly and legally issued to inventors Michael S.

Urdea, Michael P. McKenna, and Patrick A. Arensdorf by the United States Patent and Trademark Office (“PTO”) on February 21, 2012. The ’358 patent is currently assigned to HDL and expires on October 11, 2026. A true and correct copy of the ’358 patent is attached as Exhibit A.

9. The ’358 patent claims methods of using biomarkers for evaluating, *inter alia*, the risk that an individual will develop a diabetic condition.

10. On information and belief, and as indicated on Boston Heart’s website for its Prediabetes Assessment™ (http://www.bostonheartdiagnostics.com/science_portfolio_assessment.php), Boston Heart uses, sells, and offers to sell its Boston Heart Prediabetes Assessment™, which Boston Heart markets as a tool for predicting diabetes by identifying patients as low, borderline, or high risk for diabetes. On information and belief, the assessment is based on the clinical testing of various biomarkers including, but not limited to: height, weight, BMI, parental history of diabetes, use of cholesterol lowering medications, fasting glucose, glycated serum protein, adiponectin, albumin, and/or triglycerides. On information and belief, in performing its Boston Heart Prediabetes Assessment™, Boston Heart practices one or more methods claimed in the ’358 patent, including at least claim 2.

11. On information and belief, Boston Heart’s use, sale, or offer for sale within the United States of its Boston Heart Prediabetes Assessment™ directly infringes, literally and/or under the doctrine of equivalents, at least claim 2 of the ’358 patent under 35 U.S.C. § 271(a), in violation of HDL’s patent rights.

12. On information and belief, and pursuant to 35 U.S.C. § 287(a), Boston Heart has received actual notice of its infringement of the ’358 patent at least as of the filing date of this

Complaint, if not earlier. On information and belief, by receiving actual notice of its infringement of the '358 patent at least as of the filing of this Complaint, under 35 U.S.C. § 287(a), Boston Heart knew or should have known of its risk of infringing the '358 patent. By continuing to infringe the '358 patent, Boston Heart acts despite an objectively high likelihood that its actions constitute infringement of the '358 patent. Therefore, Boston Heart's continued infringement of the '358 patent renders its conduct willful and deliberate and, under 35 U.S.C. § 284, entitles HDL to treble damages.

13. On information and belief, Boston Heart's infringement of the '358 patent, together with other conduct, renders this case exceptional and, under 35 U.S.C. § 285, entitles HDL to its reasonable attorneys' fees and costs incurred in prosecuting this action.

14. On information and belief, Boston Heart's infringement of the '358 patent is ongoing. HDL will be substantially and irreparably harmed by Boston Heart's continuous infringing activities unless those activities are enjoined by this Court.

15. As a result of the foregoing, HDL has suffered monetary damages in an amount to be proved at trial.

PRAYER FOR RELIEF

WHEREFORE, HDL respectfully requests that this Court enter judgment in its favor as follows:

- (a) declare that Boston Heart's commercial use, offer for sale, and/or sale within the United States of its Boston Heart Prediabetes Assessment[™] prior to the expiration of United States Patent No. 8,119,358 constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(a);

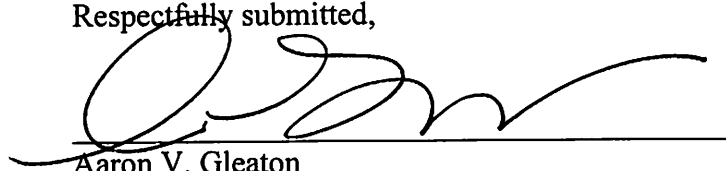
- (b) enjoin Boston Heart, and all persons acting in concert with Boston Heart, from commercially using, offering for sale, or selling Boston Heart's Prediabetes Assessment™ within the United States until the expiration of United States Patent No. 8,119,358 including any exclusivities or extensions to which HDL is or becomes entitled, in accordance with 35 U.S.C. § 283;
- (c) declare that Boston Heart's commercial use, offer for sale, and or/sale within the United States of its Boston Heart Prediabetes Assessment™ prior to the expiration of United States Patent No. 8,119,358 constitutes willful infringement of one or more claims of said patent;
- (d) order that HDL be awarded all damages under 35 U.S.C. § 284 adequate to compensate it for Boston Heart's infringement of the '358 patent; and if necessary to compensate HDL adequately for Boston Heart's infringement, that an accounting be ordered;
- (e) order that HDL be awarded treble damages under 35 U.S.C. § 284 as well as pre-judgment and post-judgment interest at the maximum rate allowed by law;
- (f) declare this to be an exceptional case and award HDL its costs, expenses, and disbursements in this action, including reasonable attorneys' fees, pursuant to 35 U.S.C. § 285; and
- (g) grant HDL such further and additional relief that this Court deems just and proper.

DEMAND FOR JURY TRIAL

HDL hereby demands trial by jury on all claims and issues so triable.

Dated: November 20, 2014

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'A. Gleaton', is written over a horizontal line.

Aaron V. Gleaton

VSB No. 83925

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

901 New York Ave, N.W.

Washington, D.C. 20001-4413

Telephone: (202) 408-4000

Facsimile: (202) 408-4400

E-mail: aaron.gleaton@finnegan.com

Attorney for Plaintiff Health Diagnostic Laboratory, Inc.

Of Counsel:

Sanya Sukduang

Lillian M. Robinson

FINNEGAN, HENDERSON, FARABOW,

GARRETT & DUNNER, LLP

901 New York Avenue, NW

Washington, DC 20001-4413

(202) 408-4000